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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,833	09/26/2000	Linda S. Mansfield	MSU 4.1-528	2531

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	6

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/669,833	Applicant(s) MANSFIELD ET AL	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. The amendment filed on 4/23/02 has been entered into the record. Claim 31 has been canceled. Claims 29,30,32,33,34 and 35 have been amended. Claims 29-30 and 32-35 are pending in the application.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

3. In view of amendment to the claims 1 and 21, the rejection under 35 U.S.C. 112, second paragraph for claims 29-30 and 32-35 is withdrawn.

4. The rejection of claims 29-30 and 32-35 under 35 U.S.C. 112, first paragraph, written description and enablement is withdrawn in view of applicant's arguments of record.

Rejection Maintained

5. The rejection of claims 29- 30 and 32-35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liang et al 1997 (Analytical Biochemistry; 250 (1) 61-5) or Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838) or Grandstrom et al 1993 (J.Vet. Diagn 5: 88-90) in view of Harlow and Lane 1988 (Antibodies; Cold Spring Harbor).

Liang et al 1997 (see page 65, right column, last paragraph) or Liang et al 1998 (see figure 1 and page 1835, right column, first paragraph, figure 3 B) disclose a purified 19KD (i.e., 16 +/- 4 antigen) antigen or 30KD antigen from S.neurona merozoites. Grandstrom et al 1993 disclose (see abstract) about 8 surface antigens including 24KD (i.e., 30 KD +/- 4) and 13KD (i.e., 16KD +/- 4).

Liang et al 1997 (see page 65, right column, last paragraph) or Liang et al 1998 (see figure 1 and page 1835, right column, first paragraph, figure 3 B), teach purified 19KD (i.e., 16 +/- 4 antigen) antigen or 30KD antigen from S.neurona merozoites are involved in humoral immunity. Grandstrom et al 1993 teaches about 8 surface antigens including 24KD (i.e., 30 KD +/- 4) or 13KD (i.e., 16KD +/- 4), which are recognized by immune serum from horses. However, the Prior art does not teach a method of producing antibodies against these proteins.

It is well known and routine in the art of immunology method of producing monoclonal antibodies and polyclonal antibodies, which bind to specific antigens or antigen epitopes. (Harlow and Lane 1988). However, the prior art does not teach specifically producing

monoclonal antibodies and polyclonal antibodies to 16KD (+/- 4) antigen or 30 KD (+/- 4) antigen from S.neurona merozoites.

Liang et al 1997 or 1998 teach the importance of surface proteins Sn14 and Sn 16 of S.neurona merozoites, which may be useful in vaccine preparation, and merozoites, which are potential targets for specific antibodies (see abstract). Further, the prior art suggests S.neurona infection of the horses induce antibodies to Sn14 and Sn 16 indicating that these proteins are strong immunogens and specific antibodies may lyse the merozoites via complement, inhibit their infection (see Discussion). Grandstrom et al also teach about the importance surface proteins including 24 KD, 13KD etc. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to raise monoclonal or polyclonal antibodies to different potent surface antigens such as 16kD or 30kD which could be used in diagnostics or to treat infection with a reasonable expectation of success because it would help to treat or cure or diagnose the infection in horses as suggested by Liang et al et al. An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art Liang et al 1997/98 or Grandstrom et al to Harlow and Lane to prepare antibodies to surface proteins because Liang et al suggests that protective humoral immunity to S.neurona infection is important. The claimed invention is prima facie obvious over Liang et al 1997 or Liang et al 98 or Grandstrom et al each in view of Harlow and Lane 1986 (chapter 6) absent any convincing evidence to the contrary.

Applicants' arguments filed on 4/23/02 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the cited art does not suggest or disclose the invention because the prior art does not teach or suggest to make polyclonal or monoclonal antibodies to 16kd antigen or 30kD antigen and as a component of fusion polypeptide. It is the examiner's position that generating antibodies to any given antigen or epitope in the recent years has become routine. Further, Campbell states " it is customary now for any group working on a macromolecule to clone the genes coding for it and make monoclonal antibodies to it (see Campbell, monoclonal antibody technology 1984, Chapter 1, page 29, under basic research) without any clear objective" (i.e., no motivation needed to make antibodies). Further, Liang et al suggests that the surface antigens 30 KD and 16 KD are strong immunogens and reacted with horse immune serum. Therefore, it is obvious to make monoclonal antibodies to different surface proteins and use them together since these antibodies could be used in various diagnostic assays and hence this rejection is maintained.

New Rejections Based on Amendment

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-30 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is rejected as being vague for the recitation of " from the serum to produce the antibody against---antigen" in step (f). Does applicant intend to mean, "isolating the antibodies from the serum that contains antibodies against 16kD and 30kd antigen?"

Claim 29 is vague in reciting, "which causes the mammal to produce----polypeptide". Does applicant intend to mean immunizing a mammal with the fusion polypeptide and adjuvant to produce antibodies?

Claims 29 and 30 are not clear and confusing. It is not clear whether applicant is claiming a method for producing an antibody against a fusion protein that comprises16kD antigen with a fusion polypeptide (i.e., for example, GST), 30kD antigen with a fusion polypeptide or 16kD and 30kD antigen with a fusion polypeptide.

Claims 32-35 are objected to as being dependent upon a rejected claim 31. Applicant is advised to amend the claims.

Claims 32-35 are rejected as being vague and not clear. For example, does applicant intend to mean " The method of claim 29 or 30 wherein the fusion polypeptide comprising protein A and the S.neurona antigen which is purified by affinity chromatography that contains IgG-linked resin or something else?"

8. Claims 29-30 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Mansfield et al U.S. Patent No. 6,153,394 in view of Harlow and Lane 1986 (chapter 6).

Mansfield et al teach immunodominant proteins, 16 KD antigen and 30KD antigen of S.neurona. However, the prior art does not teach a method of making antibodies including polyclonal or monoclonal antibodies that bind to a 16KD (+/- 4) antigen and a monoclonal antibody that selectively binds to a 30 KD (+/- 4) antigen.

It is well known and routine in the art of immunology to prepare polyclonal or monoclonal antibodies, to specific antigens (see chapter 6 of Harlow and Lane 1988) or antigen epitope. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to raise monoclonal antibodies to immunodominant surface antigens such as 16kD and 30kD with a reasonable expectation of success because it would help to treat or cure or diagnose the infection in horses as suggested by Mansfield et al (see column 4, lines 46-54). An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art Mansfield et al to Harlow and Lane to prepare monoclonal antibodies to surface proteins because Mansfield et al suggests that monoclonal antibodies can be used for more specific binding to the proteins in an immunoassay to detect S.neurona infection in horses (column 2, lines 27-29). The claimed invention is prima facie obvious over Mansfield et al in view of Harlow and Lane 1986 (chapter 6) absent any convincing evidence to the contrary

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 29-30 and 32-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 (see claims 21, 33 and 34) of U.S. Patent No. 6,344,337 in view of in view of Harlow and Lane 1988 (Antibodies; Cold Spring Harbor). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are drawn to method for producing antibodies including polyclonal and monoclonal antibodies against a 16KD +/- 4 antigen and 30 KD +/- 4 antigen of Sarcocystis neurona are obvious over the patented claims which are drawn to a monoclonal antibody against a 30 KD +/- 4 antigen of Sarcocystis neurona, a monoclonal antibody against a 16KD +/- 4 antigen of Sarcocystis neurona and a kit for detecting Sarcocystis comprising monoclonal or isolated polyclonal antibody against 16KD +/- 4 antigen of Sarcocystis neurona and isolated polyclonal antibody against 30 KD +/- 4 antigen of Sarcocystis neurona. It would have been obvious to use a method well known and routine in the art (Harlow and Lane 1988 Chapter 6) to obtain the monoclonal antibodies to 16KD +/- 4 antigen and 30 KD +/- 4 antigen of Sarcocystis neurona as taught by the prior art.

Status of Claims

11. No claims are allowed

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

7/9/02

MARK NAVARRO
PRIMARY EXAMINER